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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,985	12/11/2003	Donald E. Brodnick	039199-9544-00	8570

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EXAMINER

LIN, JACK

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/732,985	Applicant(s) BRODNICK ET AL.	
	Examiner Jack Lin	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/26/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on April 26, 2004 is acknowledged. The references listed therein have been considered.

Claim Rejections - 35 USC § 101

2. Claims 1-15 and 42-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1, 42, and 46 specify a method to acquire pulse oximetry and electrocardiogram signals from a patient. However, Claims 1, 42 and 46 do not result in a physical transformation nor do they appear to provide a useful, concrete and tangible result. Specifically, they do not appear to produce a tangible result because merely acquiring pulse oximetry and electrocardiogram signals is nothing more than a computation within a processor. They fail to use or make available for use the result of the determination to enable its functionality and usefulness to be realized. Additionally, the asserted practical application in the specification of the method to acquire pulse oximetry and electrocardiogram signals is for displaying the results to a user or caregiver. The practical application is not explicitly recited in the claims nor does it flow inherently therefrom. Therefore, Claims 1, 42, and 46 appear non-statutory.

Claims 2-15 further limit Claim 1 and Claims 43-45 further limit Claim 42 but also do not specifically or inherently produce tangible results from the method steps.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-9, 13-18, 20, 22-23, 27-33, 35, 37-38, and 42-46 are rejected under 35

U.S.C. 102(e) as being anticipated by Mills '205 (US Patent Application Publication

2002/0188205 A1). Mills '205 discloses the same invention including a method and apparatus to

monitor multiple physiological characteristics. Mills '205 discloses a probe comprising of light

emitters (paragraph 75) and detectors (paragraph 75) to measure pulse oximetry (paragraph 76)

and electrodes to measure electrocardiogram (paragraph 77). The light emitters comprise light

emitting diodes (paragraph 95) that emit light in the visible and infrared range (paragraph 82).

The detector comprises a broad-band photo detector that measures the transmitted light

(paragraph 96). Mills '205 also discloses the apparatus can comprise additional probes to allow

diagnostic-quality ECG measurements (paragraph 129). The probes are connected to a controller

comprising a computing device to generate blood oxygen saturation, ECG, and other desired

measurements (paragraph 123). Mills '205 teaches the use of the probe comprising of attaching

the probe to a patient, acquiring a pulse oximetry signal, and acquiring an ECG signal (paragraph

128). Mills '205 teaches generating a diagnostic-quality ECG by attaching multiple probes

(paragraph 129) which inherently involves acquiring a reference electrocardiogram signal and non-reference electrocardiogram signals.

Regarding Claims 6, 29 and 43, Mills '205 discloses measuring an impedance respiration signal (paragraph 153).

Regarding Claims 7, 30 and 44, Mills '205 discloses a controller to generate a cardio-respirogram signal (paragraph 123).

Regarding Claims 8, 31, and 45, Mills '205 discloses generating at least one channel of electrocardiogram output (paragraph 130 and figure 25).

Regarding Claims 20 and 35, Mills '205 discloses isolating the electrode from the detector by having separate reference wires for the electrode and detector (figure 12).

Regarding Claims 22, 37, and 46, Mills '205 discloses placing the device on the fingers of neonates and young children (paragraph 38).

Regarding Claims 23 and 38, Mills '205 discloses a probe adapted to enclose a finger in order to position the emitters and detectors on opposite sides of the finger (figure 5).

5. Claims 1, 10, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Mills '772 (US Patent Application Publication 2003/0109772 A1). Mills '772 discloses the same invention including attaching a probe to a patient, acquiring a pulse oximetry signal, and acquiring an ECG signal (paragraph 157). Mills '772 further teaches attaching a movement generator on an anesthetized patient (paragraph 26) and monitoring the depth of anesthesia (paragraph 347).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 10, 24, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills '205 as applied to claims 1, 16, and 28 above, and further in view of Rodiera Olive (US Patent 5,957,860 – cited by applicant). Mills '205 discloses the invention substantially as claimed with the exception of using a neural-muscular transmission device coupled to the substrate with the emitters, detectors, and electrodes. However, Mills '205 discloses that as a general purpose monitor, the device invites the addition of specialized add-ons (paragraph 41). Rodiera Olive teaches the use of a system that determines the neural-muscular transmission signal (column 4, lines 19-26) along with oxygen saturation and ECG (column 7, lines 38-52) in order to evaluate the status of the neuromuscular block. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the system of Mills '205 with a neural-muscular transmission device as taught by Rodiera Olive in order to evaluate the status of the neuromuscular block.

8. Claims 11, 12, 25, 26, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills '205 in view of Rodiera Olive as applied to claims 10, 24, and 39 above, and further in view of Niwa (US Patent 5,025,791). Mills '205 in view of Rodiera Olive discloses the invention substantially as claimed with the exception of filtering and ignoring the pulse oximetry signal acquired when the neural-muscular transmission signal was being

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acquired. However, Niwa discloses a processor that discards motion signals (column 6, line 67 – column 7, line 3) detected by an acceleration sensor in an oximeter device. The neural-muscular transmission device causes motion in the tissue when operating. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the system of Mills '205 in view of Rodiera Olive with a processor that discards motion signals as taught by Niwa in order to ignore and filter the pulse oximetry signal of motion signals when the neural-muscular transmission device is operating.

9. Claims 19, 21, 34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills '205 as applied to claims 16 and 28 above, and further in view of Merchant et al. (US Patent 6,023,541). Mills '205 discloses the invention substantially as claimed with the exception of a common reference wire and a multi-wire connector. However, Merchant et al. discloses a multi-wire adapter that can be connected between a probe that has its electrical elements in one configuration and a monitor designed for use with a probe having a different electrical configuration (column 2, line 65 – column 3, line 3 and figure 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the system of Mills '205 with a multi-wire adapter as taught by Merchant et al. in order to connect the probe with a monitor designed for use with a probe having a different electrical configuration.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goodman et al. (US Patent 4,938,218) discloses a perinatal pulse oximetry sensor

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comprising of an oximeter, ECG sensors, and other sensing devices. Harry et al. (US Patent Application Publication 2002/0099277 A1) discloses a vital signs monitoring sensor band used for noninvasive vital signs data including ECG, respiration, and blood oxygenation. Sackner et al. (US Patent 6,047,203) discloses a non-invasive physiological signs monitoring device comprising of a garment with electrocardiogram electrodes and various inductive plethysmographic sensors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Lin whose telephone number is (571) 272-7694. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL
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ERIC F. WINAKUR
PRIMARY EXAMINER
